DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 9, 2015

eClear International Co., Ltd.
c/o Ms. April Lee
Consultant
WithUS Consulting
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K143499
Trade/Device Name: eCligner®
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: September 3, 2015
Received: September 9, 2015

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

eClear International Co., Ltd.

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Indication for Use Statement

Indication for Use

510(K) Number (if known): K143499

Device Name: eCligner®

Indication for Use:

eCligner® is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The eCligner® is intended for minor anterior tooth movement by way of continuous gentle force.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

For FDA Use Only

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) Summary

510(k) Summary

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Device Information

- Trade (Proprietary)Name: eCligner®
- Common Name: Aligners, Sequential
- Classification Name: Orthodontic Plastic Bracket
- Product Code: NXC
- Panel: Dental
- Regulation Number: 21 CFR872.5470
- Device Class: ClassII
- Date prepared:10/08/2015

Predicate Device
Invisalign® System (K081960)

General Description

eCligner® is a transparent and removable orthodontic appliance.

eCligner® is a digitally- made Clear Aligner by the 3DCAD/CAM system. By printing the completed set-up data into a series of plastic models, eCligner® is produced by a simple stamping procedure (Vacuum forming). eCligner® is designed for orthodontic tooth movement.

Each step for using orthodontic appliance, eCligner® consists of 3 weeks (1 week for soft, 1 week for medium and 1 week for hard) and wearing the appliance 17 hours a day for each sequence is required.
* More than 3 weeks of wearing may be required per step depending on the direction of orthodontic treatment and dentist's instruction.

* eCligner® -H is used for 3 weeks during Final process.

During one individual step of treatment, three aligners of different layer thickness are worn in weekly intervals. The applied layer thicknesses are 0.5 mm (soft), 0.62 mm (medium) and 0.75 mm (hard). Each individual step is consisting of three different thickness appliances as follows:
1. eCligner® -S (Soft)
2. eCligner® -M (Medium)
3. eCligner® -H (Hard)
*eCligner® -UH (Ultra Hard, 1.00mm) is used only for the patient with Bruxism (Teeth Grinding) since the aligner can be broken while the patient grinds their teeth unintentionally.

Indication for Use

eCligner® is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e.all second molars). The eCligner® is intended for minor anterior tooth movement by way of continuous gentle force.

Mechanism of Action

Each eCligner® exerts gentle force to achieve progressive realignmen to the teeth until the final correction has been attained.

Summary of Technological Characteristics

A dental health care professional (e.g. orthodontist or dentist), prescribes the eCligner system based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth, and completes a prescription form. eCligner designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, eCligner produces the trays, which are formed of clear, thin, thermoformed plastic. The trays are sent back to the dentist who then provides them to the patient, confirming fit and design. Over a period, additional trays are provided sequentially to the patient by the physician to gradually move the target teeth to the designed position. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at anytime.

The technology is essentially identical to that used by a number of sequential alignment systems including the predicate device.

Performance Testing

Biocompatibility tests such as cytotoxicity, irritation, and sensitization were performed in accordance with ISO 10993.

In addition, software validation test for CAD/CAM system used to fabricate this subject device was performed according to Guidance for Industry and FDA Staff, Guidance for the content of premarket submissions for software contained in medical devices. A performance qualification of the available software utilized in the processing steps of the subject device has been included to support substantial equivalence.

Comparison to the Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- K081960, Invisalign system manufactured by Align Technology.

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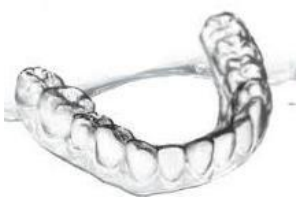
Comparison to the Predicate Devices

	Subject Device	Predicate Device
Company Name	eClear International Co., Ltd.	ALIGNTECHNOLOGY
Device Name	eCligner®	INVISALIGNSYSTEM
510(k)Number	NA	K081960
Device Classification Name	Aligner, Sequential	Aligner, Sequential
Classification Product Code	NXC	NXC
Regulation Number	21 CFR872.5470	21 CFR872.5470
Indications for Use	eCligner® is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e.all second molars). The eCligner® is intended for minor anterior tooth movement by way of continuous gentle force.	The Invisalign system is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Material	Thermoplastic	Thermoplastic
Design		
Mechanism of Action	Gentle continuous pressure on teeth	Gentle continuous pressure on teeth

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Substantial Equivalence Discussion

The eCligner® has a substantially equivalent intended use as the identified predicate. The subject device is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with 21 CFR 872.5470.

The subject and predicate devices are similar in indications, design, mechanism of action and materials.

The difference between the subject device and the predicate device is the aligners with various layer thicknesses. The subject device needs three steps of treatment with 0.5 mm (soft), 0.62 mm (medium) and 0.75 mm (hard) thickness.

The verbiage of the Indications for Use of the subject device is slightly different than that of the declared predicates; however, these slight differences in wording does not change the intended use of the subject device has compared to the declared predicate.

Any differences in technology characteristics are accompanied by information that demonstrated the device is as safe and as effective as the predicate and do not raise different questions of safety and effectiveness than the predicate.

Conclusion

Testing to demonstrate the acceptability of the software utilized in the treatment planning steps has been included to support substantial equivalence. Based on the similarities of the two devices, it is concluded that the eCligner® is substantially equivalent to the predicate device.